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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,083

04/16/2004

Rashida A. Karmali

134.004

9955

7590

01/02/2008

Rashida A. Karmali  
13th Floor  
99 Wall Street  
New York, NY 10005

EXAMINER

WARDEN, JILL ALICE

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

01/02/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/826,083

**Applicant(s)**

KARMALI, RASHIDA A.

**Examiner**

Jill A. Warden

**Art Unit**

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-10 and 12 is/are allowed.
- 6) ☒ Claim(s) 11, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm in view of Nason (4,978,504) and further in view of White (4,214,874).

Schramm teaches a method and kit for collecting samples of liquid specimens for analytical testing. See figures 2, 4 and 5. The device includes a sample container (5) with an open top (9) and a lower capillary end (4), an immunoassay test strip (12) and a vial containing reagents and/or buffers. The vial is sealed with a penetrable foil. The lower end of the container has an inwardly extending portion (6) that forms an air-tight seal with the vial. Figures 3-5 show how the device is used. See also column 4, lines 15-42. Capillary

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volume capacity is given in column 3, lines 29-31. Schramm does not teach a filter in the container, does not cite specific materials of construction, does not teach colorimetric analysis and does not teach a coated capillary.

Nason teaches a specimen test unit, see figures 12-15. The device includes top (14) and bottom caps (60) containing a swab sampling element (20) in a housing (30). The housing includes a filter for filtering samples and reagents that flow into the housing and to the collection vial. The housing is made from plastic to accommodate deformation (column 5, lines 58-62). Nason discloses colorimetric analysis on reaction products in a vial in column 9, lines 19-25 and column 10, lines 20-25. It would have been obvious to one having ordinary skill in the art to modify Schramm to provide a plastic structure for deformability and resiliency. With respect to the caps, it would have been obvious to one having ordinary skill in the art to provide caps to seal the body structure of Schramm. With respect to the filters, it would have been obvious to one having ordinary skill in the art to modify the device of Schramm to include filters to trap components or provide reagents, as suggested by Nason (column 8, lines 5-15). One would provide for colorimetric analysis within the device in order to provide an easily understood analysis method of the contents inside in order to avoid transfer of materials from the device. This would safeguard the operator and provide a single use, self-contained collection and analysis device.

Schramm and Nason do not teach coating the capillary.

White teaches a capillary tube for blood collection (see column 2, line 51 through column 3, line 17). White teaches that the interior of the tube is coated with an

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anticoagulant. Capillary attraction is used to fill the tube with blood. It would have been obvious to one having ordinary skill in the art to provide an anticoagulant coated on the interior of the capillary portion of the modified device of Schramm in order to minimize clotting from the sample being drawn through the capillary portion. Schramm and Nason include an immunoassay device. One would add the anticoagulant to ensure blood flow into the device. As for the graduated markings on the capillary, White also teaches these are conventional. It would have been obvious to one of ordinary skill in the art to add markings for volume.

***Allowable Subject Matter***

Claims 1-10 and 12 are allowed. Applicant's amendment to these claims has overcome the rejection.

***Response to Arguments***

Applicant's arguments filed October 3, 2007 with respect to claims 11, 14 and 15 have been fully considered but they are not persuasive. The argument which is specific to these claims is the presence of a coating in the capillary. Again, examiner has addressed this issue and feels that, given the teachings of the prior art, it would have been obvious to one of ordinary skill in the art to coat the capillary.

***Conclusion***

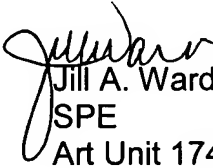
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**Conclusion**

Any inquiry concerning this communication should be directed to Jill A. Warden at telephone number (571) 272-1267.

  
Jill A. Warden  
SPE  
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